Frank D. Rodriguez (frodriguez@buddlarner.com)
Min Yang (myang@buddlarner.com)
BUDD LARNER, P.C.
150 John F. Kennedy Parkway
Short Hills, New Jersey 07078
Telephone: (973) 379-4800

Attorneys for Defendants and Counterclaim Plaintiffs Dr. Reddy's Laboratories, Inc. Dr. Reddy's Laboratories, Ltd.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD., Defendants.	Civil Action No. 15-02522- MAS-LHG *Electronically Filed*

DR. REDDY'S LABORATORIES, LTD. AND DR. REDDY'S LABORATORIES, INC.'S ANSWER AND COUNTERCLAIMS

Defendants, Dr. Reddy's Laboratories Inc. ("Dr. Reddy's Inc.") and Dr. Reddy's Laboratories, Ltd. ("Dr. Reddy's Ltd.") (collectively "DRL"), by their attorneys, answer the Complaint ("Complaint") of Plaintiffs Sanofi-Aventis U.S. LLC, Aventis Pharma S.A. and Sanofi ("Sanofi") (collectively "Plaintiffs") as follows:

THE PARTIES

1. Plaintiff Sanofi U.S. is an indirectly wholly owned U.S. subsidiary of Sanofi and is a company organized and existing under the laws of the State of Delaware, having commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807.

ANSWER

DRL is without information sufficient to admit or deny the allegations of paragraph 1 of the Complaint.

2. Plaintiff Aventis is a corporation organized and existing under the laws of France, having its principal place of business at 20 Avenue Raymond Aron, 92160 Antony, France.

ANSWER

DRL is without information sufficient to admit or deny the allegations of paragraph 2 of the Complaint.

3. Plaintiff Sanofi is a corporation organized and existing under the laws of France, having its principal place of business at 54 rue La Boétie, 75008 Paris, France.

ANSWER

DRL is without information sufficient to admit or deny the allegations of paragraph 3 of the Complaint.

4. Plaintiff Sanofi is a global research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve human and animal health.

ANSWER

DRL is without information sufficient to admit or deny the allegations of paragraph 4 of the Complaint.

5. On information and belief, defendant Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 107 College Road East, Princeton, New Jersey 08540.

ANSWER

Admitted.

6. On information and belief, defendant Dr. Reddy's Laboratories, Ltd. is a company organized and existing under the laws of India, having its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad 500 034, India.

ANSWER

Admitted.

7. On information and belief, defendant Dr. Reddy's Laboratories, Inc. is a subsidiary of Dr. Reddy's Laboratories, Ltd.

ANSWER

Admitted.

8. On information and belief, defendant Dr. Reddy's Laboratories, Inc., as United States agent for Dr. Reddy's Laboratories, Ltd. assembled and caused to be filed with the United States Food and Drug Administration ("FDA"), pursuant to 21 U.S.C. § 355(j) (Section 505(j) of the Federal Food, Drug and Cosmetic Act), Abbreviated New Drug Application ("ANDA") No. 207718 (hereinafter "the DRL ANDA") concerning a proposed drug product, cabazitaxel solution for infusion, 60 mg/1.5 mL ("DRL's Proposed ANDA Product").

ANSWER

DRL admits that Dr. Reddy's Laboratories, Inc., as United States agent for Dr. Reddy's Laboratories, Ltd., filed with the U.S. Food and Drug Administration ("FDA") ANDA No. 207718 concerning a proposed drug product, cabazitaxel injection, 60 mg/1.5 mL (40 mg/mL), for intravenous infusion.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER

Paragraph 9 asserts legal conclusions for which no answer is required. To the extent an answer may be required, DRL admits that Plaintiffs' Complaint purports to state a claim for infringement of U.S. Patent No. 8,927,592 ("the '592 patent").

10. This Court has personal jurisdiction over Dr. Reddy's Laboratories, Inc. On information and belief, Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 107 College Road East, Princeton, New Jersey 08540. On information and belief, Dr. Reddy's Laboratories, Inc. is registered as a domestic business entity with the New Jersey Department of Treasury under the business entity identification number 0100518911. On information and belief, Dr. Reddy's Laboratories, Inc. conducts business in the State of New Jersey under the alternate name Reddy-Cheminor, Inc. On information and belief, Reddy-Cheminor, Inc. is also registered as a domestic business entity with the New Jersey Department of Treasury under the business entity identification number 0100518911. On information and belief, Reddy-Cheminor, Inc. is registered to conduct business activity of distributing generic pharmaceuticals. On information and belief, Reddy-Cheminor, Inc. maintains a corporate agent for service of process at 66 South Maole Avenue, Ridgewood, New Jersey 07450. On information and belief, Reddy-Cheminor, Inc. is an agent, affiliate or subsidiary of Dr. Reddy's Laboratories, Inc.

ANSWER

DRL admits that Dr. Reddy's Laboratories, Inc. is a business registered in the State of New Jersey. Dr. Reddy's Laboratories, Inc. does not contest personal jurisdiction for the purposes of this civil action. To the extent further allegations in paragraph 10 are not addressed by the foregoing, DRL denies them.

11. On information and belief, Dr. Reddy's Laboratories, Inc. directly or through its affiliates and agents develops, formulates, manufactures, markets, imports and sells pharmaceutical products, including generic drug products, which are copies of products invented and developed by innovator pharmaceutical companies, throughout the United States, including in this Judicial District. On information and belief, Dr. Reddy's Laboratories, Inc. holds an active wholesale drug and medical device license for the State of New Jersey under License No. 5002312.

ANSWER

DRL admits that DR. Reddy's Laboratories, Inc. is in a business concerning pharmaceutical products. Dr. Reddy's Laboratories, Inc. does not contest personal jurisdiction

for the purposes of this civil action. To the extent further allegations in paragraph 11 are not addressed by the foregoing, DRL denies them.

12. On information and belief, Dr. Reddy's Laboratories, Inc. has affiliations with the State of New Jersey that are pervasive, continuous, and systematic. On information and belief, Dr. Reddy's Laboratories, Inc. engages in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of New Jersey and to the residents of the State of New Jersey, and maintenance of corporate agents in the State of New Jersey.

ANSWER

DRL admits that DR. Reddy's Laboratories, Inc. is in a business concerning pharmaceutical products. Dr. Reddy's Laboratories, Inc. does not contest personal jurisdiction for the purposes of this civil action. To the extent further allegations in paragraph 12 are not addressed by the foregoing, DRL denies them.

13. On information and belief, Dr. Reddy's Laboratories, Inc. regularly conducts and/or solicits business in the State of New Jersey, engages in other persistent courses of conduct in the State of New Jersey, and/or derives substantial revenue from services or things used or consumed in the State of New Jersey.

ANSWER

DRL admits that DR. Reddy's Laboratories, Inc. is in a business concerning pharmaceutical products. Dr. Reddy's Laboratories, Inc. does not contest personal jurisdiction for the purposes of this civil action. To the extent further allegations in paragraph 13 are not addressed by the foregoing, DRL denies them.

14. On information and belief, Dr. Reddy's Laboratories, Inc. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey, having asserted claims in this jurisdiction, including in the matter of *Dr. Reddy's Laboratories, Inc. et al. v. Purdue Pharmaceutical Products L.P. et al.*, Civil Action No. 14-3230 (JLL)(JAD) (D.N.J. May 20, 2014). On information and belief, Dr. Reddy's Laboratories, Inc. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey, having asserted counterclaims in this jurisdiction, including in the matters of *Sucampo AG et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 14-7144 (MAS)(DEA), D. I. 16 at 2-3, 18-25 (D.N.J. Jan. 26, 2015); *Helsinn Healthcare S.A. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 14-4274 (MLC)(DEA), D.I. 13 at 3, 8-12 (D.N.J. Sep. 5, 2014); *Amarin*

Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al., Civil Action No. 14-2760 (MLC)(DEA), D.I. 27 at 3, 34-48 (D.N.J. Jul. 31, 2014); *Genzyme Corp. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 13-6827 (JEI)(KMW), D.I. 17 at 6, 16-21 (D.N.J. Jan. 21, 2014).

ANSWER

Dr. Reddy's Laboratories, Inc. does not contest personal jurisdiction for the purposes of this civil action. To the extent further allegations in paragraph 14 are not addressed by the foregoing, DRL denies them.

15. Dr. Reddy's Laboratories, Inc. is also subject to personal jurisdiction in the State of New Jersey because, *inter alia*, it has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiff Sanofi U.S., having commercial headquarters in the State of New Jersey. Dr. Reddy's Laboratories, Inc. sent its March 18, 2015 Paragraph IV Notice Letter to Sanofi U.S.'s commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807. Plaintiffs' cause of action arose from Dr. Reddy's Laboratories, Inc.'s contact with Sanofi U.S. in Bridgewater, New Jersey. Dr. Reddy's Laboratories, Inc. states that it intends to engage in the commercial manufacture, use, and/or sale of DRL's Proposed ANDA Product before the expiration of U.S Patent No. 8,927,592 throughout the United States, including in this Judicial District.

ANSWER

Dr. Reddy's Laboratories, Inc. does not contest personal jurisdiction for the purposes of this civil action. DRL admits that a Notice of filing a Paragraph IV Certification for U.S. Patent No. 8,927,592 was served on Aventis on March 18, 2015 on behalf of DRL by its authorized agent, and that Plaintiffs have admitted receipt of that letter. DRL denies the remaining allegations of paragraph 15 of the Complaint.

16. On information and belief, upon approval of the DRL ANDA, Dr. Reddy's Laboratories, Inc. and/or its subsidiaries, affiliates or agents will market, sell and/or distribute DRL's Proposed ANDA Product throughout the United States, including in this Judicial District, and will derive substantial revenue therefrom.

ANSWER

DRL admits that ANDA No. 207718 was submitted to the FDA seeking approval to manufacture, use, sell, offer to sell, and import DRL's proposed cabazitaxel drug product in the United States. DRL denies the remaining allegations in paragraph 16 of the Complaint.

17. On information and belief, upon approval of the DRL ANDA, Dr. Reddy's Laboratories, Inc. and/or its subsidiaries, affiliates or agents will place DRL's Proposed ANDA Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will ultimately be purchased and used by consumers in this Judicial District.

ANSWER

DRL admits that ANDA No. 207718 was submitted to the FDA seeking approval to manufacture, use, sell, offer to sell, and import DRL's proposed cabazitaxel drug product in the United States. DRL denies the remaining allegations in paragraph 17 of the Complaint.

18. This Court has personal jurisdiction over Dr. Reddy's Laboratories, Ltd. On information and belief, Dr. Reddy's Laboratories, Ltd. directly or through its affiliates and agents develops, formulates, manufactures, markets, imports and sells pharmaceutical products, including generic drug products, which are copies of products invented and developed by innovator pharmaceutical companies, throughout the United States, including in this Judicial District. On information and belief, Dr. Reddy's Laboratories, Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products.

ANSWER

Dr. Reddy's Laboratories, Ltd. does not contest personal jurisdiction for the purposes of this civil action. DRL denies the remaining allegations of paragraph 18 of the Complaint.

19. On information and belief, Dr. Reddy's Laboratories, Ltd. has affiliations with the State of New Jersey that are pervasive, continuous, and systematic. On information and belief, Dr. Reddy's Laboratories, Ltd. engages in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of New Jersey and to the residents of the State of New Jersey, and maintenance of corporate agents in the State of New Jersey.

ANSWER

Dr. Reddy's Laboratories, Ltd. does not contest personal jurisdiction for the purposes of this civil action. DRL denies the remaining allegations of paragraph 19 of the Complaint.

20. On information and belief, Dr. Reddy's Laboratories, Ltd. regularly conducts and/or solicits business in the State of New Jersey, engages in other persistent courses of conduct in the State of New Jersey, and/or derives substantial revenue from services or things used or consumed in the State of New Jersey.

ANSWER

Dr. Reddy's Laboratories, Ltd. does not contest personal jurisdiction for the purposes of this civil action. DRL denies the remaining allegations of paragraph 20 of the Complaint.

21. On information and belief, Dr. Reddy's Laboratories, Ltd. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey, having asserted claims in this jurisdiction, including in the matter of *Dr. Reddy's Laboratories, Inc. et al. v. Purdue Pharmaceutical Products L.P. et al.*, Civil Action No. 14-3230 (JLL)(JAD) (D.N.J. May 20, 2014). On information and belief, Dr. Reddy's Laboratories, Ltd. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey, having asserted counterclaims in this jurisdiction, including in the matters of *Sucampo AG et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 14-7144 (MAS)(DEA), D. I. 16 at 2-3, 18-25 (D.N.J. Jan. 26, 2015); *Helsinn Healthcare S.A. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 14-4274 (MLC)(DEA), D.I. 13 at 3, 8-12 (D.N.J. Sep. 5, 2014); *Amarin Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 14-2760 (MLC)(DEA), D.I. 27 at 3, 34-48 (D.N.J. Jul. 31, 2014); *Genzyme Corp. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, Civil Action No. 13-6827 (JEI)(KMW), D.I. 17 at 6, 16-21 (D.N.J. Jan. 21, 2014).

ANSWER

Dr. Reddy's Laboratories, Ltd. does not contest personal jurisdiction for the purposes of this civil action. To the extent further allegations in paragraph 21 are not addressed by the foregoing, DRL denies them.

22. In the alternative, Dr. Reddy's Laboratories, Ltd. is subject to jurisdiction in the United States under the principles of general jurisdiction, and specially in the State of New Jersey pursuant to Fed. R. Civ. P. 4(k)(2). Dr. Reddy's Laboratories, Ltd. has contacts with the United States by, *inter alia*, its having filed an ANDA with the FDA.

ANSWER

Dr. Reddy's Laboratories, Ltd. does not contest personal jurisdiction for the purposes of this civil action. DRL denies the remaining allegations of paragraph 22 of the Complaint.

23. On information and belief, upon approval of the DRL ANDA, Dr. Reddy's Laboratories, Ltd. and/or its subsidiaries, affiliates or agents will market, sell and/or distribute DRL's Proposed ANDA Product throughout the United States, including in this Judicial District, and will derive substantial revenue therefrom.

ANSWER

DRL admits that ANDA No. 207718 was submitted to the FDA seeking approval to manufacture, use, sell, offer to sell, and import DRL's proposed cabazitaxel drug product in the United States. DRL denies the remaining allegations in paragraph 23 of the Complaint.

24. On information and belief, upon approval of the DRL ANDA, Dr. Reddy's Laboratories, Ltd. and/or its subsidiaries, affiliates or agents will place DRL's Proposed ANDA Product into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will ultimately be purchased and used by consumers in this Judicial District.

ANSWER

DRL admits that ANDA No. 207718 was submitted to the FDA seeking approval to manufacture, use, sell, offer to sell, and import DRL's proposed cabazitaxel drug product in the United States. DRL denies the remaining allegations in paragraph 24 of the Complaint.

25. Venue is proper in this Court at least pursuant to 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b).

ANSWER

Admitted.

JEVTANA®

26. Sanofi U.S. holds approved New Drug Application ("NDA") No. 201023 for cabazitaxel injection, 60 mg/ 1.5 mL (40 mg/mL), which is prescribed and sold in the United States under the trademark JEVTANA® KIT (hereinafter "JEVTANA®"). The FDA approved NDA No. 201023 on June 17, 2010. JEVTANA® is approved for use in combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

ANSWER

Upon information and belief, DRL admits that Sanofi U.S. is identified as the owner of New Drug Application ("NDA") No. 201023. DRL further admits that the Electronic Orange Book indicates that NDA No. 201023 was approved on June 17, 2010. Finally, DRL states that the JEVTANA® labeling and package insert speak for themselves regarding the usage and indications of JEVTANA®. DRL denies the remaining allegations in paragraph 26 of the Complaint.

THE PATENT-IN-SUIT

27. United States Patent No. 8,927,592 (the "'592 patent," copy attached as Exhibit A) is entitled "Antitumoral Use Of Cabazitaxel" and was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on January 6, 2015. The '592 patent claims, *inter alia*, methods for treating or increasing the survival of patients with prostate cancer, including the use of JEVTANA® in accordance with the labeling approved by the FDA. The '592 patent listed in the Ap*proved Drug Products With Therapeutic Equivalence Evaluations* (the "Orange Book") for JEVTANA® (NDA No. 201023).

ANSWER

DRL admits that the '592 patent indicates on its face that it was issued on January 6, 2015, the '592 patent is titled "Antitumoral Use of Cabazitaxel," what purports to be a copy of the '592 patent was attached as Exhibit A to the Complaint, and that the '592 patent is listed in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for JEVTANA KIT (NDA No. 201023). The scope of the claims of the '592 patent is a legal conclusion to which no response from DRL is required. DRL denies that the '592 patent was duly and legally issued. DRL is without information sufficient to form a belief as to the truth of the remaining allegations in paragraph 27 and therefore denies them.

28. The '592 patent is owned by Aventis.

ANSWER

DRL admits that the face of the '592 patent identifies Aventis Pharma SA as the assignee. Defendants are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 28 and therefore deny the same.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

29. On information and belief, Dr. Reddy's Laboratories, Inc. submitted the DRL ANDA to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's Proposed ANDA Product.

ANSWER

DRL admits that the DRL ANDA was submitted to the FDA seeking approval to manufacture and sell a cabazitaxel injection, 60 mg/l.5 mL (40 mg/mL), for intravenous infusion.

30. On information and belief, the DRL ANDA seeks FDA approval of DRL's Proposed ANDA Product for use in combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

ANSWER

DRL admits that the DRL ANDA was submitted to the FDA seeking approval of a cabazitaxel injection, 60 mg/l.5 mL (40 mg/mL), for intravenous infusion to obtain approval for the activities stated therein that require FDA approval. DRL indicates that the ANDA speaks for itself with respect to the use of DRL's ANDA product. DRL denies the remaining allegations of paragraph 30 of the Complaint.

31. On information and belief, Dr. Reddy's Laboratories, Inc. actively collaborated with Dr. Reddy's Laboratories, Ltd. and/or participated in and/or directed activities related to the submission of the DRL ANDA and the development of DRL's Proposed ANDA Product, was actively involved in preparing the ANDA, and/or intends to directly benefit from and has a financial stake in the approval of the ANDA. On information and belief, upon approval of the DRL ANDA, Dr. Reddy's Laboratories, Inc. will be involved in the manufacture, distribution, and/or marketing of DRL's Proposed ANDA Product.

ANSWER

DRL admits that the Dr. Reddy's Laboratories, Inc. submitted ANDA No. 207718 as United States agent for Dr. Reddy's Laboratories Ltd. to the FDA seeking approval of a cabazitaxel injection, 60 mg/l.5 mL (40 mg/mL), for intravenous infusion. DRL denies the remaining allegations of paragraph 31 of the Complaint.

32. On information and belief, Dr. Reddy's Laboratories, Ltd. actively collaborated with Dr. Reddy's Laboratories, Inc. and/or participated in and/or directed activities related to the submission of the DRL ANDA and the development of DRL's Proposed ANDA Product, was actively involved in preparing the ANDA, and/or intends to directly benefit from and has a financial stake in the approval of the ANDA. On information and belief, upon approval of the DRL ANDA, Dr. Reddy's Laboratories, Ltd. will be involved in the manufacture, distribution, and/or marketing of DRL's Proposed ANDA Product.

ANSWER

DRL admits that the Dr. Reddy's Laboratories, Inc. submitted ANDA No. 207718 as United States agent for Dr. Reddy's Laboratories Ltd. to the FDA seeking approval of a cabazitaxel injection, 60 mg/l.5 mL (40 mg/mL), for intravenous infusion. DRL denies the remaining allegations of paragraph 32 of the Complaint.

33. By letter dated March 18, 2015 (the "March 18 Notice Letter"), and pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. §314.95, Dr. Reddy's Laboratories, Inc. notified Plaintiffs that it had submitted to the FDA the DRL ANDA, seeking approval to engage in the commercial manufacture, use, or sale of DRL's Proposed ANDA Product before the expiration of the '592 patent. The March 18 Notice Letter was received by Plaintiff Sanofi U.S. on March 20, 2015.

ANSWER

DRL admits that it sent a detailed Notice of Certification regarding U.S. Patent No. 8,927,592, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) to Plaintiffs on March 18, 2015 notifying Plaintiffs that DRL had filed a Paragraph IV Certification that the '592 patent is invalid, unenforceable, and/or will not be infringed by DRL's proposed ANDA product, and that Plaintiffs have admitted receipt of that letter.

34. In its March 18 Notice Letter, Dr. Reddy's Laboratories, Inc. notified Plaintiffs that it had filed a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") with respect to the '592 patent in support of the DRL ANDA. On information and belief, Dr. Reddy's Laboratories, Inc. certified that the '592 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of DRL's Proposed ANDA Product.

ANSWER

DRL admits that it sent a detailed Notice of Certification regarding U.S. Patent No. 8,927,592, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95(c) to Plaintiffs on March 18, 2015 notifying Plaintiffs that DRL had filed a Paragraph IV Certification that the '592 patent is invalid, unenforceable, and/or will not be infringed by DRL's proposed ANDA product, and that Plaintiffs have admitted receipt of that letter.

35. The DRL ANDA refers to and relies upon Sanofi U.S.'s NDA No. 201023 for JEVTANA®.

ANSWER

DRL admits that the DRL ANDA identifies the reference-listed drug as JEVTANA®, which is described in NDA 201023. DRL denies the remaining allegations in paragraph 35 of the Complaint.

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 8,927,592

36. Plaintiffs repeat and reallege paragraphs 1 through 35 above as if fully set forth herein.

ANSWER

DRL realleges its responses to paragraphs 1-35 of the Complaint as if fully set forth herein.

37. By submitting the DRL ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of DRL's Proposed

ANDA Product throughout the United States prior to the expiration of the '592 patent, Defendants committed an act of infringement of the '592 patent under 35 U.S.C. § 271(e)(2).

ANSWER

Denied.

38. If Defendants commercially make, use, offer to sell, or sell DRL's Proposed ANDA Product within the United States, or import DRL's Proposed ANDA Product into the United States, or induce or contribute to any such conduct during the term of the '592 patent, they would further infringe the '592 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER

Denied.

39. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '592 patent. Plaintiffs do not have an adequate remedy at law.

ANSWER

Denied.

40. Dr. Reddy's Laboratories, Inc.'s certification under 21 U.S.C. §355(j)(2)(A)(vii)(IV) against the '592 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

ANSWER

Denied.

ANSWER TO PRAYER FOR RELIEF

DRL denies that Plaintiffs are entitled to the judgment or other relief prayed for in Paragraphs A-G under the heading "Prayer for Relief" in the Complaint.

AFFIRMATIVE DEFENSES

First Affirmative Defense

Plaintiffs fail to state a claim upon which relief can be granted.

Second Affirmative Defense

Claims of the '592 patent are invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103 and/or 112, and/or for non-statutory (obviousness-type) double patenting.

Third Affirmative Defense

DRL has not infringed, induced infringement or contributed to the infringement, and DRL will not infringe, induce infringement or contribute to the infringement, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '592 patent.

Fourth Affirmative Defense

Plaintiffs may not seek injunctive relief against DRL because Plaintiffs alleged damages are not immediate or irreparable, and Plaintiffs therefore have an adequate remedy at law.

Fifth Affirmative Defense

Plaintiffs may not seek attorney's fees against DRL because Plaintiffs have not alleged, and cannot prove, that this is an exceptional case under 35 U.S.C. § 285.

Sixth Affirmative Defense

Plaintiffs may not seek treble damages under 35 U.S.C. § 284 because Plaintiffs have not alleged, and cannot prove that DRL engaged in willful and deliberate infringement.

Seventh Affirmative Defense

Any additional defenses that discovery may reveal.

COUNTERCLAIMS

Counterclaim Plaintiffs Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's Inc.") and Dr. Reddy's Laboratories, Ltd. ("Dr. Reddy's Ltd."), (collectively, "DRL"), for their Counterclaims against Counterclaim Defendants Sanofi-Aventis U.S. LLC, Aventis Pharma S.A. and Sanofi ("Sanofi") (collectively "Plaintiffs"), allege and aver as follows:

THE PARTIES

1. Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 107 College Road East, Princeton, NJ 08540. Dr. Reddy's Laboratories, Inc. is a subsidiary of Dr. Reddy's Laboratories, Ltd. Dr. Reddy's Laboratories, Ltd. is an Indian public limited liability company incorporated and existing under the laws of India and having a principal place of business at Door No 8-2-337, Road No 3, Banjara Hills, Hyderabad - 500034, Andhra Pradesh, India.

2. Counterclaim-Defendant Sanofi-Aventis U.S. LLC ("Sanofi U.S.") has pled that it is a U. S. subsidiary of Sanofi and is a company organized and existing under the laws of the State of Delaware with commercial headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. Counterclaim-Defendant Aventis Pharma S.A. ("Aventis") has pled that it is a corporation organized and existing under the laws of France with a principal place of business at 20 avenue Raymond Aron, 92160 Antony, France.

4. Counterclaim-Defendant Sanofi has pled that it is a corporation organized and existing under the laws of France with a principal place of business at 54 rue La Boetie, 75008 Paris, France.

JURISDICTION AND VENUE

5. This is an action for a declaratory judgment, together with such further relief based thereon as may be necessary or proper, pursuant to the Federal Declaratory Judgment Act 28 U.S.C. §§ 2201 and 2202. The basis for a declaratory judgment is, as fully appears below, an actual controversy between Counterclaim Plaintiffs and Counterclaim Defendants arising under the United States Patent Laws, Title 35 of the United States Code.

6. This Court has subject matter jurisdiction over the action based on 28 U.S.C. §§ 1331 and 1338.

7. This Court has personal jurisdiction over Counterclaim Defendants at least because Counterclaim Defendants voluntarily filed, in this Court, the Complaint to which these Counterclaims are directed.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400.

FACTUAL BACKGROUND

Patent-in-Suit

9. Sanofi U.S. has alleged that it holds New Drug Application ("NDA") No. 201023, by which the United States Food and Drug Administration ("FDA") granted approval of cabazitaxel injection, 60 mg/1.5 mL (40 mg/mL), for intravenous infusion.

10. Upon information and belief, Sanofi U.S. has listed U.S. Patent No. 8,927,592 ("the '592 patent") (the "patent-in-suit") in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") as covering the JEVTANA® drug product and methods for using it.

11. On or about January 6, 2015, the United States Patent and Trademark Office ("PTO") issued the '592 patent, entitled "Antitumoral Use of Cabazitaxel."

12. The '592 patent indicates on its face that it is assigned to Aventis Pharma S.A., and patent assignments on the United States Patent and Trademark Office website indicate no further assignment.

13. Aventis has alleged ownership of the patent-in-suit.

14. Sanofi U.S. holds NDA No. 201023, by which the FDA granted approval for the manufacture and sale of cabazitaxel injection, 60 mg/1.5 mL (40 mg/mL), for

intravenous infusion, which Sanofi U.S. markets and sells under the trade name JEVTANA®.

15. DRL submitted Abbreviated New Drug Application ("ANDA") No. 207718 to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). ANDA No. 207718 contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") indicating that the '592 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of DRL's ANDA product.

16. DRL made an Offer of Confidential Access to its ANDA No. 207718 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III), in its March 18, 2015, Notice Letter.

17. On April 6, 2015, Counterclaim-Defendants initiated this civil action, CA. No. 3:15-cv-02522, against Counterclaim-Plaintiffs in this judicial district, alleging infringement of the '592 patent.

18. Counterclaim-Plaintiffs seek a declaratory judgment that the '592 patent is not infringed and/or is invalid.

FIRST COUNTERCLAIM

(Declaratory Judgment of Non-Infringement of United States Patent No. 8,927,592)

19. Counterclaim-Plaintiffs restate and re-allege each of the foregoing paragraphs 1-18 of the counterclaims as if fully set forth herein.

20. Counterclaim-Defendants have alleged that DRL's filing of ANDA No. 207718 infringes the '592 patent.

21. As evidenced by Counterclaim-Defendants' Complaint and Counterclaim-Plaintiffs' Answer in this action, there is an actual, substantial, and continuing justiciable case or

controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding the alleged infringement of the '592 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

22. The manufacture, use, sale, offer for sale, and/or importation by DRL of its proposed product pursuant to ANDA No. 207718 will not infringe, directly or indirectly, any valid claim of the '592 patent under any provision of 35 U.S.C. § 271.

23. The proposed ANDA product, which would be marketed upon approval of ANDA No. 207718, does not and will not infringe, directly or indirectly, any valid and enforceable claim of the '592 patent, either literally or under the doctrine of equivalents.

24. Counterclaim-Plaintiffs are entitled to a judicial determination that the proposed product which is the subject of ANDA No. 207718 does not and will not infringe, directly or indirectly, any valid and enforceable claim of the '592 patent, either literally or under the doctrine of equivalents.

SECOND COUNTERCLAIM

(Declaratory Judgment of Invalidity of United States Patent No. 8,927,592)

25. Counterclaim-Plaintiffs restate and re-allege each of the foregoing paragraphs 1-24 of the counterclaims as if fully set forth herein.

26. As evidenced by Counterclaim-Defendants' Complaint and Counterclaim-Plaintiffs' Answer in this action, there is an actual, substantial, and continuing justiciable case or controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding the validity of the claims of the '592 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

27. This counterclaim is for a declaration that the claims of the '592 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including failure to comply with one or more of 35 U.S.C. §§

101, 102, 103, and 112 for and any other ground provided by 35 U.S.C. § 282, and/or based on other judicially-created bases for invalidity.

DRL'S REQUEST FOR RELIEF

WHEREFORE, DRL respectfully requests that:

(a) Judgment be entered that the Complaint against DRL is dismissed with prejudice and that Plaintiffs and Counterclaim Defendants take nothing thereby;

(b) Judgment be entered that the commercial manufacture, use, offer to sell, sale or import of the products which are the subject of DRL's ANDA 207718 do not and will not infringe, directly or indirectly, any valid and enforceable claim of United States Patent 8,927,592, either literally or under the doctrine of equivalents;

(c) Judgment be entered that each claim of United States Patent 8,927,592 is invalid;

(d) The Court permanently enjoin Plaintiffs and Counterclaim Defendants or any of their assigns or successors from asserting that the commercial manufacture, use, offer to sell, sale or import of the products which are the subject of DRL's ANDA 207718 infringes or will infringe any claim of United States Patent 8,927,592;

(e) This case be deemed an exceptional case within the meaning of 35 U.S.C. § 285;

(f) DRL be awarded its attorney fees and costs of suit; and

(g) The Court award DRL such other and further relief as this Court may deem necessary, just and proper.

Respectfully submitted,

Dated: June 26, 2015

s/ Frank D. Rodriguez

Frank D. Rodriguez
Min Yang
BUDD LARNER, P.C.
150 John F. Kennedy Parkway
Short Hills, New Jersey 07078
Telephone: (973) 379-4800
frodriguez@buddlarner.com
myang@buddlarner.com

Attorneys for Defendants and Counterclaim Plaintiffs Dr. Reddy's Laboratories, Inc. Dr. Reddy's Laboratories, Ltd.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is related to the following civil actions, all of which are pending in the District of New Jersey:

- Sanofi-Aventis U.S. LLC et al v. Fresenius Kabi USA, LLC, C.A. Nos.14-7869 & 15-2631 (MAS)(LHG);
- Sanofi-Aventis U.S. LLC et al. v. Accord Healthcare, Inc., C.A. Nos. 14-8079 & 15-2520 (MAS)(LHG);
- Sanofi-Aventis U.S. LLC et al. v. BPI Labs, LLC, C.A. Nos. 14-8081 & 15-2521 (MAS)(LHG);
- Sanofi-Aventis U.S. LLC et al. v. Apotex Corp., C.A. No. 15-287 & 15-1835 (MAS)(LHG);
- Sanofi-Aventis U.S. LLC et al. v. Breckenridge Pharma., Inc., C.A. No. 15-289 & 15-1836 (MAS)(LHG);
- Sanofi-Aventis U.S. LLC et al. v. Onco Therapies Ltd., C.A. No. 15-290 & 15-3392 (MAS)(LHG);
- Sanofi-Aventis U.S. LLC et al. v. Actavis LLC et al., C.A. No. 15-776 & 15-3107 (MAS)(LHG); and
- Sanofi-Aventis U.S. LLC et al. v. Glenmark Generics Inc. et al., C.A. No. 15-776 & 15-3107 (MAS)(LHG).

I certify under penalty of perjury that the foregoing is true and correct.

Executed on June 26, 2015
Short Hills, New Jersey

s/ Frank D. Rodriguez
Frank D. Rodriguez

CERTIFICATE OF SERVICE

I, Frank D. Rodriguez, do hereby certify that on June 26, 2015, I caused a true and correct copy of **DR. REDDY'S LABORATORIES, LTD. AND DR. REDDY'S LABORATORIES, INC.'S ANSWER AND COUNTERCLAIMS** to be served via ECF and e-mail on counsel for plaintiff:

Liza M. Walsh
CONNELL FOLEY LLP
85 Livingston Avenue
Roseland, New Jersey 07068-1765

William E. Solander
Jason A. Leonard
FITZPATRICK, CELLA, HARPER & SCINTO
1290 Avenue of the Americas
New York, NY 10104-3800

Dated: June 26, 2015

s/ Frank D. Rodriguez
Frank D. Rodriguez